PATIENT RECOMMENDATION FOR ELECTRICAL STIMULATION EQUIPMENT USAGE FROM A LICENSED HEALTHCARE PROFESSIONAL

The specifications for the Neuromuscular Electrical Stimulation (NMES) equipment being recommended for this specific patient's use require a four channel stim system featuring up to 440 volts maximum output per channel, output at a maximum average amperage over the Pulse Train On/Off Cycle of no more than 4.4 mAmps per channel via AC Output. These specifications have been cleared for safe home use by the FDA for the following applications:

1) Increase local blood circulation (move out edema)
2) Re-educate muscles
3) Relax muscle spasms
4) Maintain or increase range of motion
5) Prevent or retard disuse atrophy
6) Prevent Venous Thrombosis through immediate calf stimulation post-surgery.

Please print legibly below.

Patient Name: _____ Referral Date: _____

Patient Address: _____

Phone: _____ Email: _____ Gender: M / F

Patient issues to be treated with the NMES device: _____

_____

Clinic Name_____

Provider's Name: _____

Provider's Address: _____

Provider's Phone: _____Provider's Fax _____ Email:_____

Many Patients with the following CONTRAINDICATIONS have benefitted significantly from home NMES treatments with the periodic oversight of their Healthcare Provider. Please call 702-871-3200 for alternate treatment options and guidance in treating patients with the following CONTRAINDICATIONS:

1. Implanted pacemaker/defibrillator unless exception is granted by pacemaker manufacturer.*
2. Patients with current Thrombosis/Phlebitis
3. Patients with uncontrolled Epilepsy or seizure within past year
4. Directly over the top of Cancerous Lesions
5. Directly over Varicose Veins
6. Pregnant Patients across the pelvis (Can be treated elsewhere but no exceptions for pelvic region)

Ordering Healthcare Professional's signature: X_____ Date_____

My signature above signifies that I am a Licensed Healthcare Professional in my state of operation and I am recommending that the above described patient use a NMES device with the specifications described above.

Note to Providers: In general, an order for the use of NMES equipment may come from any licensed Healthcare Professional including; MDs, Dos, NDs, Nurses, PAs, Nurse Practitioners, DCs, PTs, L.Ac, NPs, DDS, Massage Therapists, etc. With the above Contraindications, an appropriate specialist should sign. *Pacemaker Exception Policy form attached below on next page.

Return this completed form by fax at 702-446-6506, mail to; Rehaba, Inc., 38954 Proctor Blvd., #158, Sandy, OR 97055 or email it to greg@rehaba.com. For more information, please call 702-871-3200.

General Rehaba Neuromuscular Electrical Stimulator (NMES) Patient Usage Policy For Patients with an Implanted Heart Pacemaker and/or Defibrillator

In the past 50 years hundreds of different NMES devices have received clearance for marketing by the FDA via FDA 510 Certification. The FDA has had a long standing policy to make the use of any implanted heart pacemaker or defibrillator device a *recommended* Contraindication for the use of any Electrical Stimulator device. This includes NMES devices with low amperage output.

This FDA *recommended* contraindication was based years ago on the presence in the marketplace of older model pacemakers that were sensitive to microwave ovens and to some old technology "Burst Mode" TENS unit stimulators that were shown to interfere with the proper operation of some pacemaker devices. Since such old "Burst Mode" TENS units are still available the old FDA *advised* contraindication is still in place even though the more modern pacemakers are not as susceptible to such interference.

Because the recommended NMES device operates at an extremely low maximum amperage alternating current average output (zero to maximum of 4.4 milliamps averaged over the entire Pulse train On/Off Cycle) which output is nearly 2,300% lower than other electrical stimulation devices which traditionally operate at a maximum amperage of 90 milliamps, NMES devices that do not exceed this low amperage average output do not have enough amperage at maximum operational amperage to interfere with the operation of an implanted pacemaker or defibrillator. We call the technology in such NMES devices with these specs true Tesla Based Technology™ or TBT for short.

Over the years at least one pacemaker manufacturer has actually hooked up TBT electrical stim devices to test their low amperage output devices with electrodes hooked directly to either side of different pacemaker/defibrillator devices to see if the low average amperage output could cause such heart pacemaker/defibrillators to malfunction. **In such tests, the low maximum average amperage output described above has never once been shown to interfere with the proper operation of heart pacemaker/defibrillator (PD) devices even under such extreme conditions with the electrodes attached directly to the PD device.**

To date there has never been even one report of any TBT low average amperage output device interfering in any way with the proper functioning of an implanted pacemaker/defibrillator in any treated heart patient with such an implanted device.

Many heart patients struggle with edema build up in their lower extremities which fluid buildup increases post capillary pressure in the matrix of fluid around the cells. This pressure can back up through the capillaries slowing the velocity of blood flow from the arteries as the heart is forced to push against the increased pressure caused by the edema. The only thing that moves the lymph is muscle contractions, but many of these patients cannot tolerate the exercise needed to create sufficient full resistance exercise needed to move out the edema. A device featuring the specs described above in paragraph 3 is capable of producing deep muscle contractions which patients can tolerate for extended time periods allowing enough targeted full resistance exercise to move out the lymph, thus reducing post capillary pressure and returning the arterials to normal velocity.

Under normal circumstances there is no danger at all in treating a pacemaker/defibrillator patients lower extremities with a low amperage NMES device. While tests of the true Tesla Based Technology™ NMES device have not been able to intentionally cause a pacemaker to malfunction, when it comes to protecting patients, caution should rule and so even such a super safe low amperage TBT NMES device is not recommended to be used transthoracically on pacemaker/defibrillator patients. Even away from the heart it is possible that a situation could arise in treating a patient's lower leg and foot where one of the electrodes could lose its sticking capability over time and fall off during a treatment. A patient could forget to turn the unit off and could pick up the electrode that had fallen off the left leg with their right hand changing the current path from the proper path (outside of the shin [anterior tibialis] to the bottom of the foot) instead to a new path from the right hand across their heart and down their trunk to their left foot. This is the kind of exceptional situation that could arise that could cause the current inadvertently to go right across the pacemaker. For this reason, any patient who is approved by their heart specialist to use a TBT NMES device needs to be fully informed to turn the unit off immediately if one of the electrodes accidentally falls off to avoid the above described scenario.

If a clinician desires to approve a heart pacemaker/defibrillator patient to use a TBT NMES device to move out the edema in their lower extremities the clinician may want to provide the patients pacemaker manufacturer with the low amperage specification of the device so that the pacemaker manufacturer can send a letter to the clinician authorizing the non-thoracic use of the TBT stimulator to move out edema.

Our TBT NMES device operates at a maximum average output amperage of just 4.4 milliamps. It is high milliamperage that can cause a malfunction in a pacemaker and a NMES device with such low average amp output cannot output enough amperage to interfere.

Any pacemaker device manufacturer should be able to authorize the use of such a low amperage muscle stimulator on one of their pacemaker using patients when the electrical device is only used on the patient's lower extremities and is not used across the chest.

Clinicians seeking to help their heart pacemaker patients move out edema by use of a our low average amperage NMES system can contact Rehaba at 702-871-3200 for guidance in obtaining clearance from the Pacemaker manufacturer for the patient to use such a low amperage device on their lower legs to reduce edema and therefore reduce the pressure the heart must pump against.

In more than 20 years of testing and more than one million treatments monitored, there has never been even one negative incident reported where such a TBT low average amperage output NMES device interfered with the proper function of an implanted pacemaker or defibrillator.